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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,441	11/19/2003	J. Donald Hill	018880.0147	3943

24735 7590 09/27/2006

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EXAMINER	
KOTINI, PAVITRA	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,441	HILL ET AL.	
	Examiner	Art Unit	
	Pavitra Kotini	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *1-12 and 23-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-22 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/14/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

In discussion with the applicant over the phone on Tuesday September 6th, 2006, the applicant agreed to cancel claims 1-12, 23-33 without prejudice.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 13-22 and 35 are drawn to a method for connecting two conduits and delivering a coupler into a blood vessel and , classified in class 128, subclass 898.

II. Claim 34, drawn to a coupler holder and delivery device, classified in class 606, subclass 108.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process as claimed can be practiced with another materially different product such as a catheter system used to deliver and deploy the coupler for connecting two conduits. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the

inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

During a telephone conversation with attorney Jim Arpin on Tuesday, September 6th, 2006 a provisional election was made without traverse to prosecute the invention of Group I, claims 13-22 and 35. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-12, 23-34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 13-22 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson (US 20050192604) in view of Akin (20020161383).

Regarding **claim 13**, Carson discloses positioning a first saddle (14, fig. 3B) of a first coupler (298, fig. 21C) within a first conduit (W, fig. 3B); clamping said first conduit (42, fig. 3B) to said first saddle of said first coupler; and connecting said first coupler (298, fig. 21C) and said second coupler (296, fig. 21C). Referring to attached appendix, Carson also discloses a second saddle (A, fig. 21C) of a second coupler (296, fig. 21C). Carson does not expressly disclose positioning the second coupler within a second conduit.

However, Akin teaches a first conduit (9, fig. 2) and a second conduit (10, fig. 2) and a method for a side-to-side vessel anastomosis with an apparatus that has an analogous structure to Carson's device. This arrangement and methodology would allow for fluid communication between two parallel conduits. Therefore, it would have been obvious to a person of ordinary skill in the art, at the time of the invention, in view of Akin, to modify the method as disclosed by Carson to be used for coupling two conduits as taught by Akin to gain the advantage stated above.

As to **claim 14 and 15**, Carson discloses the step of making an incision in said conduit and positioning said saddle of said coupler within said conduit (para. 0070; I, fig. 5A).

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson in view of Akin as applied to claim 13 above, and further in view of Gifford (US 20020151914).

Carson in view of Akin discloses the invention substantially as claimed above, except for changing the temperature of the tissue clamp. However, Gifford teaches the step of heating an anastomosis device to a transition temperature, such that the device is secure within the conduit (last senstence of para. 0216). This process has the apparent advantage of preventing fluids leaking from the artificial opening under normal physiological conditions. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the coupler disclosed by Carson in view of Akin to secure it to the vessel by the process taught by Gifford.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson in view of Akin as applied to claim 13 above, and further in view of Berreklouw (WO 00/24339).

Carson in view of Akin discloses the invention substantially as claimed above, except for a pair of legs formed in the tissue clamp. However, Berreklouw teaches a pair of legs (11, 111 fig. 4, 5) that could be incorporated on the tissue clamp for further securing of the coupler to the vessel wall (col.16, lines 30-36). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify

the coupler disclosed by Carson in view of Akin to include legs as taught by Berreklouw for the sake of enhancing the fitting of the coupler to the vessel wall.

Regarding **claim 20**, Carson discloses positioning a first flange (See attached appendix, C, fig. 21C) of said first coupler (298, fig. 21C) in alignment with a second flange (B, fig. 21C) of said second coupler (296, fig. 21C). Carson does nto expressly disclose a clamping ring. However, Akin discloses a clamping ring (122, fig. 11B) that provides the apparent advantage of securing the first coupler and second coupler together between the first and second flanges. Therefore, it would have been obvious to a person of ordinary skill in the art, at the time of the invention to modify the connection of the two connectors disclosed by Carson by a securement part such as a clamping ring taught by Akin to ensure a tight, leak-proof connection between the couplers.

Regarding **claim 21**, Carson discloses engaging a first mating surface (see attached appendix, F, fig. 21C) of said first coupler (298, fig. 21C) and a second mating surface (E, fig. 21C) of said second coupler (296, fig. 21C).

Regarding **claim 22**, Carson discloses a coupler apparatus that illustrates a first coupler and a second coupler connected together without the couplers being positioned within vessels (fig. 21c). Therefore, this figure illustrates that the couplers can be assembled together prior to placement within the conduits.

Regarding **claim 35**, Carson discloses engaging said channel (30, fig. 1A) of said coupler (12, fig. 1A); engaging said tissue clamp (16, fig. 1A); making an incision into said blood vessel (para. 0021; I, fig. 5A); delivering said coupler into said blood vessel through said incision (fig. 5A); securing said saddle to said blood vessel (para. 0023, 14,

fig. 3B); and releasing said tissue clamp (64, fig. 5B), so that said tissue clamp conforms to said saddle (fig. 5B). Carson does not expressly disclose bending of the tissue clamp. However, Akin teaches bending of parts of the two-piece anastomosis device (104, 96, fig. 11B). Since, the coupler disclosed by Carson and the anastomosis device of Akin are both made from any suitable material, It would have been obvious to a person of ordinary skill in the art, in view of Akin, at the time of the invention to bend the tissue clamp disclosed by Carson in a similar manner as taught by Akin for separating the saddle from the tissue clamp and allowing for easier placement of the saddle within the lumen.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Stevens (US 2002 0116018) discloses an anastomosis system and method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M & W-F 9:00am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pavitra Kotini
AU 3731

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
9/18/06